REMARKS

The present invention is directed to methods and compositions for the treatment of cancer comprising the administration of neuraminidase. In particular, the present invention is directed to methods and compositions for treating cancer wherein the effective amount of the neuraminidase is extremely low.

After entry of this amendment, Claims 1-2, 4-9 and 13-17 will be pending. Based on the following remarks, Applicant respectfully requests reconsideration and allowance of the pending claims. Claims 1 and 17 have been amended. Support for this amendment is found throughout the specification and particularly at page 2, lines 22-23 and page 5, lines 12-15. No new matter is introduced by the amendments.

Rejection Under 35 U.S.C. § 112, first paragraph (written description)

In the March 9, 2004 Office Action, Claims 1, 2, 4-9 and 13-16 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicant respectfully traverses this rejection to the extent that it is applied to the claims as amended.

The claims have been amended to remove the rejected phrase "wherein the composition does not contain tumor cells". Therefore the rejection is moot, and withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. § 112, first paragraph (enablement)

In the March 9, 2004 Office Action, Claims 1, 2, 4-9 and 13-17 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled. Applicant respectfully traverses this rejection to the extent that it is applied to the claims as amended.

The Examiner provided five articles to support an allegation that treatment of cancer is "highly unreliable and not yet achieved" and therefore the claimed method is non-enabled.

Applicant respectfully disagrees. Applicant submits that the cited articles are between 5 and 14 years old, and that they would necessarily be considered outdated by one skilled in the art. Since the publication of the articles, significant advances have been made in the area of cancer treatment.

With the millions of research dollars that are spent studying the pathology and treatment of cancer, the knowledge of cancer and development of cancer treatments is increasing exponentially daily. A very recent report from the American Cancer Society (July 2004)[1] describes how survival rates have increased dramatically in the last 30 years according to a report published by the Center for Disease Control and Prevention (CDC) and the National Cancer Institute (NCI). "The report attributed the improvements in survival to several factors, including *better treatments*, better prevention of cancer recurrences and secondary cancers, and lower death rates from other causes." (emphasis added)

"The percentage of people in the entire population who die of any type of cancer -- the death rate -- has been decreasing since the early 1990s. Death rates have declined for 11 of the top 15 cancers in men and 8 of the top 15 cancers in women." Clearly the survivors and their families would disagree with the Examiner's assertion that treatment of cancer has not yet been achieved.

Furthermore a search of the U.S. Patent Office database of issued patents yielded at least 1,633 issued patents with the terms "method", "treatment" and "cancer" in the claims. It is unlikely that 1,633 U.S. patents are not enabled on the basis that "treatment of cancer is highly unreliable and not yet achieved".

The present claims are directed to a method for treating a human with cancer by administering a composition of neuraminidase. Details of the dosage amount and administration protocols are clearly described in detail on pages 4-6 of the specification. Furthermore, and contrary to the Office Action, Applicant has successfully reduced to practice the claimed method. "A single working example in the specification for a claimed

[1] "More People Surviving Cancer", http://www.cancer.org/docroot/NWS (copy provided herewith).

invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled." MPEP 2164.02

Applicant has provided five examples in the specification that disclose successful treatment of cancer with the claimed method. Example 4 discloses the successful treatment of prostate, testicular, intestinal, liver and pancreatic cancer. Example 5 discloses the successful treatment of Lung and liver cancer. Examples 6 and 7 disclose the successful treatment of inoperable brain tumors. Example 8 discloses the successful treatment of lymphoma. The Declaration of Dr. Kline (November 26, 2003) filed with the response dated December 2, 2003 discusses eight patients that were successfully treated using the claimed method.

The claimed method is described in sufficient detail to enable one of skill in the art to use the claimed method with a reasonable expectation of success. The level of skill in the art is high, explicit doses and formulations are provided as is the presence of working examples. A detailed analysis of the factors for enablement dictated in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) clearly provide enough support that the disclosure satisfies the enablement requirement. The legal standard has been met and accordingly, applicant requests reconsideration and withdrawal of the rejection.

Rejection Under 35 U.S.C. § 103

In the March 9, 2004 Office Action, Claim 17 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Sedlacek '86 or Sedlacek '87, in view of Green, Kline '133 or Kline '863. Applicant respectfully traverses this rejection to the extent that it is applied to the claims as amended.

> "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion of motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claims limitations." (MPEP 2143)

Both Sedlacek 1986 and 1987 employ the chessboard vaccination method to administer neuraminidase with mitomycin-treated tumor cells as follows.

> "For chessboard vaccination, increasing numbers of tumor cells were combined with increasing amounts of VCN, resulting in multiple combinations of tumor cells and VCN. All these combinations were simultaneously and separately, injected intradermally (i.d.) into the tumor bearing animal. (Sedlacek 1987, p. 842)"

This administration protocol clearly describes injection of variable concentrations of tumor cells in combination with neuraminidase at a single time point, not a dosing regimen to treat cancer. The claims of the present application have been amended herein to reflect this element and describe a multiple dose/day administration protocol for treatment and maintenance phases.

A multiple dose/day administration treatment protocol would not be obvious in view of the disclosure of either Sedlacek reference. Sedlacek discloses a vaccination protocol (See abstracts for both references). There would be no reason to immunize an animal more than once a day because the immune system would still be coping with the initial injection. One of ordinary skill would not be motivated to administer the neuraminidase composition as disclosed by Sedlacek multiple times a day. The claimed dosing regimen provides an effective amount of neuraminidase in the circulation for a longer period than disclosed by Sedlacek. Green and Kline '133 and Kline '863 to not disclose multi-dose/day administration of neuraminidase or provide a reason why multiple daily doses of neuraminidase would be preferable. All claim elements are not disclosed by the prior art nor made obvious. Absent the teachings of the present specification, one of ordinary skill would not be motivated to combine the cited references and arrive at the claimed method. The legal standard is met.

CONCLUSION

The foregoing is a complete response to the Office Action mailed March 9, 2004. Applicant respectfully submits that the present application is in condition for immediate allowance. An early notification is earnestly solicited. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 11-0855. If the Examiner has any questions, or further issues remain to be resolved, the Examiner is requested to contact the undersigned at (404) 745-2463.

Respectfully submitted,

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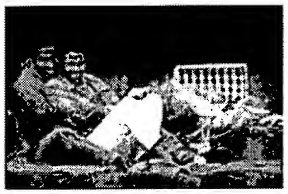
More People Surviving Cancer

Report Counts Nearly 10 Million US Survivors

Article date: 2004/07/14



The past 30 years have seen a steady increase in the number of cancer patients who survive the disease, according to a recent report by the Centers for Disease Control and Prevention (CDC) and the National Cancer Institute (NCI).

In 2001, 9.8 million Americans were cancer survivors, the report said, while in 1971 just 3 million people fell into that category. The agencies used data from a national disease registry, the NCI's Surveillance, Epidemiology, and End Results (SEER) Program, to compile their statistics.

The report attributed the improvements in survival to several factors, including better treatments, better prevention of cancer recurrences and secondary cancers, and lower death rates from other causes. Earlier diagnosis of the disease because of wider screening is also important, but the researchers noted that some people may be living longer with cancer simply because they were diagnosed earlier, not because their outcomes are actually better.

The new report comes on the heels of another major study of cancer trends, the Annual Report to the Nation on the Status of Cancer, prepared by the American Cancer Society, CDC, NCI, and the North American Association of Central Cancer Registries.

That report also found improvements in survival, and lower death rates and incidence rates for many cancers.

The percentage of people in the entire population who die of any type of cancer -- the death rate -- has been decreasing since the early 1990s. Death rates have declined for 11 of the top 15 cancers in men and 8 of the top 15 cancers in women.

Survival rates -- the percentage of people who get cancer and survive at least 5 years -- have also improved substantially for most of the top 15 cancer sites in men and women.

One of the most promising findings of the report was that the lung cancer incidence rate is declining in women for the first time. And lung cancer deaths among women have stabilized, after increasing for many years.

Not all Americans are benefiting from the improvements in cancer detection and treatment, however. The report found wide disparities in survival among racial and ethnic minorities.

Nevertheless, public health experts said the recent findings are hopeful signs in the fight against cancer. The challenge now, the CDC/NCI report said, is to find better ways to help cancer survivors and their families through better understanding of the long-term health and social consequences of surviving cancer.

ACS News Center stories are provided as a source of cancer-related news and are not intended to be used as press releases.

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Results of Search in 1976 to present db for:
((ACLM/method AND ACLM/cancer) AND ACLM/treatment): 1633 patents.
Hits 1 through 50 out of 1633

Next 50 Hits

Jump To

Refine Search ACLM/method AND ACLM/cancer AND ACLM/treatm

	PAT. NO.	Title
1	6,767,926	Method for protecting normal cells from cytotoxicity of chemotherapeutic agents
2	6,765,104	Transition metal complexes of n, n',n"trialkyl-cis-1,3,5-triaminocyclohexane and related compositions and methods of synthesis and use
3	6,765,013	Thiazolidinedione derivatives for the treatment of diabetes and other diseases
4	6,765,008	Pyrrolopyrimidines as CRF antagonists
5	6,762,205	Phenyl sulfamate derivatives
6	6,762,198	Dihetero-substituted metalloprotease inhibitors
7	6,762,192	Tetrahydronaphthyridinyl-carboxamides having anti-convulsant activity
8	6,759,509	Branched peptide linkers
9	6,759,426	3-(Imidazolyl)-2-aminopropanoic acids
10	6,759,197	Microchip arrays of regulatory genes
11	6,759,064	Compositions based on vanilloid-catechin synergies for prevention and treatment of cancer
12	6,756,504	Sphingolipids
13	6,756,399	Use of lipoxygenase inhibitors and PPAR ligands as anti-cancer therapeutic and intervention agents
14	6,753,340	(4,2-disubstituted-thiazol-5-yl)amine compounds as PDE7 inhibitors
15	6,752,990	High affinity humanized anti-TAG-72 monoclonal antibodies
16	6,750,220	Amine salt of an integrin receptor antagonist
17	6,750,217	Benzenesulfonamide derivatives and their use as MEK inhibitors
18	6,750,215	Substituted benzoxazines as integrin antagonists